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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,641	08/30/2001	Yasushi Sato	0263-4051	9688

7590 09/26/2003  
Morgan & Finnegan  
345 Park Avenue  
New York, NY 10154

EXAMINER

KEMMERER, ELIZABETH

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/914,641

Applicant(s)

SATO, YASUSHI

Examiner

Elizabeth C. Kemmerer, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 January 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Election/Restriction***

Applicant's election with traverse of protein species G-CSF (I-A) and the combination of phenylalanine, arginine and methionine (II-T) in Paper No. 6 (06 January 2003) is acknowledged. The traversal is on the ground(s) that the proteins G-CSF, EPO and PTH do not constitute independent contributions to the art, and examination of all species would not be burdensome. Similarly, Applicant argues that the generically claimed amino acids of combinations thereof do not constitute independent contributions to the art, and examination of all species would not be burdensome. This is found persuasive, and thus the species are rejoined

### ***Status of Application, Amendments, Ad/Or Claims***

The preliminary amendment filed 29 February 2000 (Paper No. 3) has been entered in full. Claims 1-30 are under examination.

### ***35 U.S.C. § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims either recite "accelerated testing" or depend from claims that recite such. It is unclear from the specification and the prior art

what is meant by "accelerated testing" and how it is different from "unaccelerated testing".

**35 U.S.C. § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 6-18 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/14465 (Boehringer Mannheim GmbH, published 07/07/94; of record, IDS filed 30 August 2001; English translation attached). In the following rejection, page numbers refer to the English translation.

WO 94/14465 teaches a stable G-CSF formulation comprising phenylalanine and arginine wherein the formulation has stability characteristics consistent with the residual ratios recited in the claims (re: claims 1-4; see p. 21; Table 2 for formulation; p. 21, Table 3 and p. 23, Table 5 for stability data). The formulations are substantially free from protein as a stabilizer (re: claim 6; see Tables 2, 4, 6, 9; formulations listed at pp. 26, 31, 34, 35 and 37). The G-CSF is in lyophilized form (re: claim 7; p. 19, for example). The formulations contained mannitol and a surfactant (re: claims 8 and 9; p. 28). The formulations contained polysorbate 80 (re: claims 10 and 11; p. 34). The formulations had a pH of 6.5 (re: claims 12-14 and 16-18; p. 22). The G-CSF was produced from CHO cells (re: claim 15, p. 5).

Claims 19-30 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 63-146829 (Chugai Pharmaceutical Co., Ltd., published 06/18/88; of record, IDS filed 30 August 2001; English translation attached). In the following rejection, page numbers refer to the English translation.

JP 63-146829 teaches a stabilized G-CSF formulation containing methionine and arginine which inherently does not substantially produce a variant oxidized at methionine (re: claims 19, 20, 28, 29; pp. 3-4, item 5; paragraph bridging pp. 10-11). The formulation is substantially free from protein as a stabilizer (re: claims 21, 30; pp. 17-18, Table I). Also taught is a method for inhibiting physiologically active G-CSF from producing a variant oxidized at a methionine residue comprising adding methionine to the composition (re: claims 22-25; pp. 10-11) and wherein other proteins are not used as stabilizers (re: claim 26; pp. 17-18, Table I). Finally, JP 63-146829 teaches the method wherein the G-CSF is in lyophilized ("freeze-dried") form (re: claim 27; p. 10).

### **35 U.S.C. § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/144465 (of record) in view of JP 63-146829 (of record).

WO 94/144465 teaches a stable G-CSF formulation comprising phenylalanine and arginine, as discussed *supra*.

WO 94/144465 does not teach a G-CSF formulation further comprising methionine. However, JP 63-146829 recognized that the addition of methionine to a G-CSF formulation served to stabilize the formulation (see discussion *supra*).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the G-CSF + phenylalanine + arginine formulation of WO 94/144465 by adding methionine as suggested by JP 63-146829 with a reasonable expectation of success. The motivation to do so is provided by both references' teachings regarding the benefits of adding phenylalanine, arginine and methionine, and the appreciation of one skilled in the art that addition of any agent that contributes to stability would have been desirable.

Thus, the claimed invention as a whole was clearly *prima facie* obvious over the prior art.

### **Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (703) 308-2673. The examiner can normally be reached on Monday through Thursday, 6:30 a.m. to 4:00 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler, Ph.D. can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*Elizabeth C. Kemmerer*

ECK

ELIZABETH KEMMERER  
PRIMARY EXAMINER

**ATTACHMENT 1 – ENGLISH TRANSLATION OF WO 94/144465**



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**ATTACHMENT 2 – ENGLISH TRANSLATION OF JP 63-146829**